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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/636,123	08/10/2000	Wolfgang Biesel	2565/76	6322
26646	7590	09/22/2004	EXAMINER	
KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004			MACHUGA, JOSEPH S	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/636,123	<b>Applicant(s)</b> BIESEL, WOLFGANG	
	<b>Examiner</b> Joseph S. Machuga	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on 16 June 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3-5 and 7-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-5 and 7-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### ***Response to Arguments***

Applicant's arguments have been given careful consideration but are not deemed persuasive. In the Zuk, Jr. #5472605 device blood flow from tube 13 passes through leukocyte filter 103 into chamber 109. Likewise, in the Verkaart #4466888 device blood flows from tube 60 through filter 70 and into a lower collection chamber. The vacuum source (not shown) drives the fluid through the system and is connect to all the systems components directly or indirectly through tube 54. Currently, contrary to applicant's arguments, it appears to be an obvious substitution of one filter 103 for another 70. The motivation to do so would be to remove leukocytes from the blood. Since the leukocyte filter 103 is hydrophilic and as such would allow blood to pass through so no substantial redesign of the system is seen as needed, as argued in the response.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3, 5, 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verkaart #4466888 in view of Zuk, Jr. #5472605 and Biesel et al 5607830.
3. Verkaart discloses an autologous blood transfusion device (column 1, lines 14-16.) The device includes a blood collection tank, a filter (70) and means for generating a vacuum (54.) The reference also teaches that a centrifuge unit can be mounted downstream (column 4, lines 54-60.) Not disclosed by this reference is the filter specifically designed for leukocytes or tumor cells and the specifics of the centrifuge.
4. Zuk et al discloses a filter assembly. The device includes a housing and flat internal filter assembly. The filter assembly is especially adapted to remove toxins such as leukocytes from blood.
5. Biesel et al discloses an autologous blood centrifuge. The design is especially designed for continuous processing. This feature eliminated the need to remove or drain the centrifuge bowl as with the prior art devices. It also has the advantage of operating in the presence of a small or limited amount of blood such as that would be seen with infants.
6. Given these teachings, it would have been obvious to one of ordinary skill in the art to modify Verkaart's device to include a filter capable of removing toxins such as

leukocytes given Zuk et al's teaching that this is old and well known in the art. It would also have been obvious to one of ordinary skill in the art to use a centrifuge such as that disclosed by Biesel et al in place of the centrifuge in Verkaart's device given the references teaching that this centrifuge eliminates the need to remove or drain the centrifuge bowl as with the prior art devices and has the added advantage of being able to operate in the presence of a small or limited amount of blood such as that would be seen with infants.

7. Claims 4, 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verkaart #4466888 in view of Zuk, Jr. #5472605 and Biesel et al #5607830 as applied to claims 1, 3, 5, 7 and 9 above, and further in view of Papillon et al 5643193.

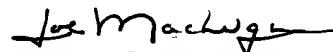
8. Papillon discloses a blood-processing device. The reference teaches adding an anticoagulant and wash solution to the system prior to filtering the blood in the blood supply line to prevent deterioration of the fluid.

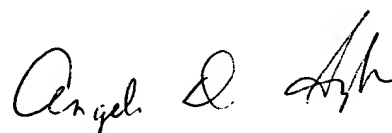
9. Given this reference it would have been obvious to one of ordinary skill in the art to an anticoagulant and wash solution to the blood processing system of the proposed combination upstream of the filter assembly to prevent deterioration of the fluid given Papillons teaching that this is old and well know.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Machuga whose telephone number is 703-305-6184. The examiner can normally be reached on Monday-Friday; 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Joseph S. Machuga  
Examiner  
Art Unit 3762

  
**ANGELA D. SYKES**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 3700**